Complete Summary

GUIDELINE TITLE

Adult low back pain.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Adult low back pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Sep. 64 p. [115 references]

GUI DELI NE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Adult low back pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Sep. 63 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the <u>FDA</u> Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the <u>FDA Web site</u> for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Acute low back pain
- Chronic low back pain
- Acute sciatica
- Chronic sciatica

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Chiropractic
Family Practice
Internal Medicine
Orthopedic Surgery
Physical Medicine and Rehabilitation
Radiology
Sports Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the use of the recommended conservative approach as first-line treatment, such as activity and self-care for patients with low back pain
- To reduce unnecessary imaging studies in patients with acute low back pain

• To increase the appropriate assessment of patients with chronic low back pain

TARGET POPULATION

Adult patients age 18 and over in primary care who have symptoms of low back pain or sciatica

Note: The guideline focuses on acute and chronic management, including indications for medical nonsurgical/surgical referral. For workers' compensation patients, see the mandated Workers' Compensation Guidelines at http://www.revisor.leg.state.mn.us/.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

- 1. Phone triage or medical screening evaluation
- 2. Medical history, including evaluation of cancer risk factors, spinal infection, Cauda Equina signs and symptoms, neurologic involvement, and psychosocial factors
- 3. Physical examination including palpation for spinal tenderness, neuromuscular testing, and bilateral straight leg raise
- 4. Laboratory testing (complete blood test [CBC] and erythrocyte sedimentation rate) if suspicion of cancer or infection
- 5. Lumbar spine x-rays (anterior to posterior [AP] and lateral [LAT] views) for specific indications
- 6. Symptom classification by duration and location
- 7. Early referral to physical therapy or spine care specialist

Treatment/Management

- 1. Home self care, including patient education, anti-inflammatory medication (e.g., aspirin, ibuprofen, naproxen sodium); or acetaminophen; ice packs or heat as preferred on sore area; careful reintroduction of activity, along with stretches and walking; safe back exercises; and stress management
- 2. Acute low back pain and acute sciatica:
 - Conservative treatment, including patient education; cold and heat therapies; analgesic medication; muscle relaxants; and activity recommendations including exercise programs
 - Discharge (return to work) or comprehensive reevaluation
 - Follow-up visits that include subjective pain rating, functional assessment, and clinician's objective assessment
 - Referral to physical therapist or other trained spine care specialist
- 3. Chronic low back pain:
 - Lumbar spine x-rays (anterior to posterior and lateral views)
 - Active rehabilitation including patient education (proper body mechanics), resumption of normal light activities, exercise program, management of psychosocial factors, and multidisciplinary approach
 - Consultation with/referral to a medical nonsurgical back specialist
- 4. Chronic sciatica:
 - Lumbar spine computed tomography or magnetic resonance imaging if patient is potential surgical candidate

- Other special diagnostic tests (bone scan, electromyography, computed tomography enhanced myelogram, myelogram, and radionuclide studies) for specific indications
- Active rehabilitation
- Epidural steroid injection
- Consultation with/referral to a surgical back specialist

Primary Prevention

- 1. Patient education about posture and the proper performance of job activities
- 2. Work site analysis, ergonomics, and exercise

MAJOR OUTCOMES CONSIDERED

- Number, duration, and intensity of pain episodes and recurrences
- Change in functional status (strength, mobility, endurance) associated with low back pain
- Time required to return to work
- Utilization of health care resources
- Diagnostic accuracy of various imaging techniques including lumbar spine computed tomography, magnetic resonance imaging, and computed tomography myelography
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

Randomized, controlled trial

Class B:

Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report
- B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline annotation, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member groups during an eight-week review period.

Each of the Institute's participating member groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating member groups following implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group

Following the completion of the review period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the responses received from member groups. Two members of the Committee on Evidence-Based Practice carefully review the input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of four questions: (1) Is there consensus among all ICSI member groups and hospitals on the content of the guideline document? (2) Has the drafting work group answered all criticisms reasonably from the member groups? (3) Within the knowledge of the appointed reviewer, is the evidence cited in the document current and not out-of-date? (4) Is the document sufficiently similar to the prior edition that a more thorough review (critical review) is not needed by the member group? The committee then either approves the guideline for release as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Member groups may introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for three-six months. At the end of the pilot test phase, ICSI staff and the leader of the work group conduct an interview with the member groups participating in the pilot test phase to review their experience and gather comments, suggestions, and implementation tools.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline; the Committee on Evidence-Based Practice reviews the revised guideline and approves it for release.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include: combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to Summary of Changes -- September 2005.

The recommendations for the management of adult low back pain are presented in the form of an algorithm with 25 components, accompanied by detailed annotations. An algorithm is provided for <u>Adult Low Back Pain</u>; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III and Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

- Cauda Equina syndrome is a condition requiring emergent evaluation and surgery. A patient should be referred immediately to the emergency room (ER) if any of the following emergent symptoms are present: (Annotations #1, 2)
 - Sudden onset or otherwise unexplained loss or changes in bowel or bladder control (retention or incontinence)
 - Sudden onset or otherwise unexplained bilateral leg weakness
 - Saddle numbness
- 2. A patient should be offered an appointment within 24 hours if any of the following symptoms are present (Annotation #2):
 - Fever 38 degrees C or 100.4 degrees F for greater than 48 hours
 - Unrelenting night pain or pain at rest
 - Pain with distal (below the knee) numbness or weakness of leg(s)
 - Leg weakness
 - Progressive neurological deficit

- Patient requests for same day appointment
- 3. Lumbar spine x-rays should be limited to red flag indications (Annotation #4):
 - Unrelenting night pain or pain at rest
 - Fever above 38 degrees C or 100.4 degrees F for greater than 48 hours
 - Progressive neuromotor deficit
 - Pain with distal numbness or leg weakness
 - Loss of bowel or bladder control (retention or incontinence)
 - Clinical suspicion of ankylosing spondylitis
 - Significant trauma
 - History of or suspicion of cancer
 - Osteoporosis
 - Chronic oral steroids
 - Immunosuppressed or on immunosuppression medication
 - Drug or alcohol abuse
- 4. Red flag and psychosocial indicators should be reviewed and evaluated at each contact/visit. While there is no outcome data related to this, an assessment that includes a subjective pain rating, functional assessment, and a clinician's objective assessment should be done at each visit. (Annotations #1, 4, 12, 17, 18)
- 5. Emphasize patient education and conservative home self-care which includes limited bed rest, early ambulation, postural advice, gentle stretching, use of ice/heat, anti-inflammatory and analgesic over-the-counter medication, and early return to work or activities. (Annotation #5)
- 6. Based on history and physical, classify symptoms by duration and location into appropriate categories: (Annotation #10)
 - Acute low back pain
 - Chronic low back pain
 - Acute sciatica
 - Chronic sciatica
- 7. The natural history of low back pain is most patients will experience partial improvement in 4 to 6 weeks and will have a recurrence of low back pain in 12 months. (Annotations #5, 12)

Patients with acute low back pain should be advised to stay active and continue ordinary daily activity within the limits permitted by the pain. For chronic back pain, there is evidence that exercise therapy is effective. (Annotation #12)

- 8. Consideration should be given to epidural steroid injections if patient is being considered for surgical interventions. Epidural steroid injections should not be done without fluoroscopic guidance. (Annotation #24)
- 9. Referrals for advanced imaging studies should be limited to patients with (Annotation #22):
 - Progressive neurological deficits and
 - Minimal to no improvement of radicular symptoms despite 6 weeks of conservative treatment
 - Uncontrolled pain
 - Cauda Equina Syndrome

Adult Low Back Pain Algorithm Annotations

1. Patient Calls/Presents with Low Back Pain or Sciatica

Key Points:

- Medical screening for low back pain should be performed via triage evaluation.
- If low back pain may be related to a possible Workman's Compensation, it is important to follow the Worker's Compensation Treatment Guidelines.

The patient calls the clinic or presents as a walk-in at the clinic. A medical screening should be performed via triage/evaluation for phone contact and via provider examination for walk-ins. Each medical group may modify this proposed movement as needed.

The triage evaluation should first rule out emergent condition such as Cauda Equina Syndrome.

General Assessment:

- Recent back procedure or epidural anesthesia
- Location of pain:
 - Low back pain (LBP) (does not radiate past the knee)
 - Sciatica (LBP with radiation past the knee)
- Duration of symptoms, including date of injury or onset of symptoms:
 - 6 weeks or less is acute
 - More than 6 weeks is chronic
- If injury: How did injury occur?
- Unrelenting or severe pain
 - Scale of 0 to 10, with 10 indicating most severe pain
- Other medical conditions
- History of previous back pain or surgery
- Psychosocial indications

For Worker's Compensation patients see the mandated Worker's Compensation Treatment Guidelines. (http://www.revisor.leg.state.mn.us/).

Patient Education Regarding Primary Prevention

Providers in clinic systems are encouraged to provide primary education through other community education institutions/businesses to develop and make available patient education materials concerning back pain prevention and care of the healthy back. Emphasis should be on patient responsibility, workplace ergonomics, and home self-care treatment of acute low back pain. Employer groups should also make available reasonable accommodations for modified duties or activities to allow early return to work and minimize the risk of prolonged disability. Education of frontline supervisors in occupational strategies to facilitate an early return to work and to prevent prolonged disabilities is recommended.

Evidence supporting this recommendation is of class: R

2. Emergent or Urgent?

Emergent - refer to emergency room for immediate evaluation

- Sudden onset or otherwise unexplained loss or changes in bowel or bladder control (retention or incontinence)
- Sudden onset or otherwise unexplained bilateral leg weakness
- Saddle numbness

Urgent - appointment within 24 hours:

- Fever 38 degrees C or 100.4 degrees F for greater than 48 hours
- Unrelenting night pain or pain at rest
- Pain with distal (below the knee) numbness or weakness of leg(s)
- Leg weakness
- Progressive neurological deficit
- Patient requests same day appointment

3. Evaluation Indicated?

Appointment within 2 to 7 days if the answer to any of the following is positive:

- Exertion injury (e.g., lifting, digging, reaching)
- History of back symptoms has been seen before, at least once
- Chronic back pain lasting longer than 6 weeks
- Unexplained weight loss (greater than 10 pounds in 6 months)
- Over age 50
- History of cancer

4. Primary Care Evaluation and X-Ray Indications

Key Points:

- Consider factors that may prolong disability
- Generally anterior to posterior (AP) and lateral (LAT) views x-rays are not helpful in the acute setting

This includes a history and physical and consideration of psychosocial factors.

If a serious underlying disease such as cancer, Cauda Equina syndrome, significant or progressive neurologic deficit, or other systemic illness is present, consult or refer.

Patient History Includes:

Cancer risk factors:

- 50 years old or older
- History of cancer
- Unexplained weight loss

 Failure to improve after 4 to 6 weeks of conservative low back pain therapy

If all four of the above risk factors for cancer are absent then studies suggest that cancer can be ruled out with 100% sensitivity.

Risk factors for possible spinal infection:

- Intravenous (IV) drug use
- Immunosuppression
- Urinary infection

Signs and symptoms of Cauda Equina Syndrome:

- Urinary retention (if no urinary retention then the likelihood of Cauda Equina Syndrome is less than 1 in 10,000)
- Saddle anesthesia, unilateral or bilateral sciatica, sensory and motor deficits, and abnormal straight leg raising are all common.

Signs or symptoms of neurologic involvement:

- Complaint of numbness or weakness in the legs
- Sciatica with radiation past the knee (increases the likelihood of a true radiculopathy rather than pain radiating only to the posterior thigh)
- Sciatica has such a high sensitivity (95%) that its absence makes lumbar disc herniation unlikely
- The likelihood of disc herniation in a patient without sciatica would be 1 in 1,000
- Because more than 95% of lumbar disc herniations occur at the L4-5 or L5-S1 levels, the neurologic exam should focus on the L5 and S1 nerve roots; however, upper lumbar nerve root involvement may be suggested when pain conforms to L2, L3, or L4 dermatomal distribution and is accompanied by anatomically congruent motor weakness or reflex changes

Psychosocial indications:

- Belief that pain and activity are harmful
- "Sickness behaviors" such as extended rest
- Depressed or negative moods, social withdrawal
- Treatment that does not fit best practice
- Problems with claim and compensation
- History of back pain, time off, or other claims
- Problems at work or low job satisfaction
- Heavy work, unsociable hours
- Overprotective family or lack of support

Psychosocial indications can be barriers to recovery. Consider factors such as fear, financial problems, anger, depression, job dissatisfaction, family problems, or stress which can contribute to prolonged disability. Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical

Systems Improvement (ICSI) guideline <u>Major Depression in Adults in Primary</u> Care for more information.

(See Annotation Appendix B, "Psychosocial Screening and Assessment Tools" in the original guideline document.)

Physical Examination Should Document:

Palpation for spinal tenderness

Neuromuscular testing to include:

- Ankle dorsiflexion strength
- Great toe dorsiflexion strength
- Ankle reflexes
- Knee reflexes
- Sensory exam with pinprick sensation in the medial, dorsal, and lateral aspects of the foot
- Significant or progressive neuromotor deficit requires surgical consultation

Straight leg raise (SLR) should be assessed bilaterally to evaluate for nerve root impingement, including but not limited to disc herniation.

- Positive straight leg raise is defined as pain in the posterior leg that radiates below the knee with the patient lying supine and the hip flexed 60 degrees or less, is suggestive of disc herniation.
- Negative straight leg raise rules out surgically significant disc herniation in 95% of cases.

Laboratory Evaluation

Consider a CBC (complete blood count) and erythrocyte sedimentation rate if suspicion of cancer or infection.

May consider early referral to physical therapy or another trained spine therapy professional. (See Annotations #14, "Consider Referral to a Trained Spine Therapy Professional" and #20, "Refer/Consult Non-surgical Back Specialist" for details on specialties and treatments.)

- Patient presents with severe incapacitating, disabling back, or leg pain; or
- Significant limitation of functional or job activities

Lumbar spine x-ray (AP and LAT views) indications

Generally AP and LAT x-rays are not useful in the acute setting but may be warranted when:

• Over 50 years old (increased risk of malignancy, compression fracture)

- Unrelenting night pain or pain at rest (increased incidence of clinically significant pathology)
- History or suspicion of cancer (rule out metastatic disease)
- Fever above 38 degrees C (100.4 degrees F) for greater than 48 hours
- Osteoporosis
- Neuromotor or sensory deficit
- Chronic oral steroids
- Immunosuppression
- Serious accident or injury (fall from heights, blunt trauma, motor vehicle accident)--this does not include twisting or lifting injury unless other risk factors are present (e.g., history of osteoporosis)
- Failure to respond to 4 to 6 weeks of conservative therapy
- Drug or alcohol abuse (increased incidence of osteomyelitis, trauma, fracture)
- Clinical suspicion of ankylosing spondylitis

Oblique x-rays are not recommended; they add only minimal information in a small percentage of cases, and more than double the exposure to radiation.

Evidence supporting this recommendation is of classes: C, R

5. Home Self-Care Treatment Program

Key Points:

- Low back pain is common and most patients significantly improve in 4 to 6 weeks.
- The long-term course of low back pain is typically a return to previous activities though often with incomplete recovery of pain.
- Patients should be re-evaluated if there is not significant improvement in 1 to 3 weeks or symptoms progress.

When patients are improving they should continue self-care as outlined. Document the phone triage and home self-care treatment in the patient's medical record (e.g., no appointment is needed at this time, patient is improving with home self-care instructions and will call back if questions arise or condition changes).

Etiology

- Pain in the lower back is very common. It can be related to certain activities, poor posture, physical stress, or psychological stress. Ninety percent of back pain patients improve within 4 to 6 weeks.
- Consider telling the patient that approximately two-thirds of the people
 who recover from a first episode of acute low back symptoms will have
 another episode within 12 months. Unless the back symptoms are very
 different from the first episode or there is a new medical condition,
 improvement can be expected from each episode.
- When pain or weakness lasts longer than 6 weeks, more specialized treatment(s) may be needed. For this reason it is important for the patient to keep the doctor informed of his or her progress.

• Other etiologies include pregnancy, labor, menstrual period, urinary tract problems, stomach upset with nausea, vomiting, or diarrhea

Instruct the patient to:

- Carefully introduce activities back into his/her day as he/she begins to recover from the worst of the back pain episode. Gradual stretches and regular walking are good ways to get back into action.
- Ice packs or heat as preferred on the sore area will keep the inflammation down and short duration in a position of comfort may be helpful.
- Use over-the-counter anti-inflammatory medications (e.g., aspirin, ibuprofen, naproxen sodium) or acetaminophen to help ease the pain and swelling in the lower back. If stomach complaints persist, call your provider
- Learn safe back exercises like modified sit-ups and low back stretches. Make them a regular part of your lifestyle.
- Take time to relax. Tension will only make your back feel worse.

Instruct the patient to call back in 1 to 3 weeks if:

- No improvement with home management
- Significant pain persists beyond a week
- Symptoms persist, worsen, or progress
- Improvement in symptoms, reinforcement of self-care program

9. Consult or Refer

Complete a diagnostic workup or refer to appropriate medical specialty for serious underlying conditions (e.g., cancer, or other systemic illness.) Each medical group may have other indications for specialty referral.

Consult or refer to neurosurgery or surgical orthopedics if:

- The patient is surgical candidate.
- Signs or symptoms of Cauda Equina Syndrome are present.
- Signs or symptoms of progressive or significant neuromotor deficit (e.g., foot drop or functional muscle weakness such as hip flexion weakness or quadriceps weakness) are present.
- Neuromotor deficit persists after 4 to 6 weeks of conservative treatment (does not include minor sensory changes or reflex changes).
- The patient has chronic sciatica with positive straight leg raise (SLR) longer than 6 weeks.

Consult or refer to neurology (limited special indications)

- The patient has chronic sciatica longer than 6 weeks.
- The patient has atypical chronic leg pain (negative SLR).
- The patient has new or progressive neuromotor deficit.

10. Is Pain Acute or Chronic?

There is a considerable number of International Classification of Diseased, 9th Revision (ICD-9) diagnosis codes for low back pain (LBP). These four narrative diagnostic categories suffice to describe LBP. This guideline uses these four categories to indicate appropriate treatment. Each medical group should determine appropriate codes to identify these 4 classifications. This simplified diagnostic classification system reduces unnecessary variation in the number of ICD-9 codes used and also allows for research to link these codes with treatment interventions and outcome measures. In the absence of symptoms that suggest serious underlying disease (e.g., cancer, Cauda Equina Syndrome, significant or progressive neurologic deficit or other systemic illness), use one of these four low back pain diagnoses:

- Acute low back pain: LBP that does not radiate past the knee with current symptoms 6 weeks or less from onset
- Chronic low back pain: LBP that does not radiate past the knee with current symptoms more than 6 weeks from onset
- Acute sciatica: LBP that radiates past the knee with current symptoms
 6 weeks or less from onset
- Chronic sciatica: LBP that radiates past the knee with current symptoms more than 6 weeks from onset

A patient with "recurrent acute" episodes will follow the acute algorithm when the current symptoms are 6 weeks or less from onset. "Recurrent acute" means symptoms at some point improved, separating the current episode from previous episodes. When the current symptoms are more than 6 weeks from onset the patient should be regarded as chronic and the provider should move to the corresponding sections of the algorithm (box 16 and beyond in the original guideline document). Sacroiliac joint dysfunction may be a contributor to low back pain and radicular pain in some individuals. This needs to be considered as a potential origin of pain.

If at initial evaluation the patient is identified as chronic LBP, see Annotation # 17, "Chronic Low Back Pain." For chronic sciatica see Annotation #22.

12. Conservative Treatment

Key Points:

- Most patients who experience low back pain will have a recurrence within 12 months.
- Remaining active leads to a more rapid recovery with less chronic pain.
- Bed rest is not recommended. If the patient must rest, bed rest should be limited to no more than two days.
- It is important to evaluate non-physical factors that may impact returning to work or ongoing disability.
- The longer term course of low back pain is typically of a return to previous activities though often with incomplete recovery of pain.

Conservative Treatment:

- Most patients who seek attention for their back pain will improve within two weeks. Most patients experience significant improvement within four weeks.
- Approximately two-thirds of the people who recover from a first episode of acute low back symptoms will have another episode within 12 months. Unless the back symptoms are very different from the first episode or the patient has a new medical condition, expect improvement to be similar for each episode.
- Recommend cold packs or heat as preferred by the patient.
- Recommend analgesic medication for short-term (less than 3 months) symptom control. Clinicians should consider the risk and benefits of any medication and prescribe the lowest effective dose possible.
- Muscle relaxants are sometimes helpful for a few days but can cause drowsiness.
- Narcotic analgesics are rarely indicated
- If the patient has been involved in home care and has had an adequate trial prior to the first visit, consider referral to a spine therapy professional on the initial visit. (See Annotation #14, "Consider Referral to a Spine Care Specialist.")

Activity Recommendations:

Patients with acute low back pain should be advised to stay active and continue ordinary daily activity within the limits permitted by the pain. Remaining active leads to more rapid recovery with less chronic disability and fewer recurrent problems than either bed rest or back mobilizing exercises. [Conclusion Grade I: See Conclusion Grading Worksheet -- Appendix A -- Annotation #12, (Conservative Treatment)]

- Activity modification
 - Continue routine activity while paying attention to correct posture.
 - Patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back especially while lifting.
 - Activity recommendations for the employed patient with acute low back symptoms need to take into consideration the patient's age and general health, and the physical demands of the patient's job.
 - Patients should discontinue any activity or exercise that causes spread of symptoms (peripheralization).
- Bed rest
 - Bed rest is not recommended. If the patient must rest, bed rest should be limited to no more than two days and only as an option for patients with severe initial symptoms of primarily leg pain.
 - A gradual return to normal activities is more effective and leads to more rapid improvement with less chronic disability than prolonged bed rest for treating acute low back problems.

 Prolonged bed rest for more than 4 days may lead to debilitation and is not recommended for treating acute low back problems.

Exercise

- Patients should discontinue any activity or exercise that causes spread of symptoms (peripheralization)
- Low stress aerobic and flexibility exercise can prevent debilitation due to inactivity during the first month of symptoms and thereafter may help to return patients to the highest level of functioning appropriate to their circumstances.
- Recommended exercise quotas that are gradually increased result in better outcomes than telling patients to stop exercising if pain occurs. Aerobic (endurance) programs which minimally stress the back (walking, biking, or swimming) can be started during the first 2 weeks for most patients with acute low back problems.
- Strengthening exercises for trunk muscles (especially back extensors), gradually increased, are helpful for patients with low back problems.

During the first 2 weeks, strengthening exercises may aggravate symptoms since they mechanically stress the back more than endurance exercise. It is important to consult with a medical specialist such as a qualified spine specialist who can evaluate individual symptoms and recommend a safe and effective program. Self-treating with an exercise program not specifically designed for the patient may aggravate your symptoms.

Self Care Brochure (See Support for Implementation Recommended Resources in the original guideline document):

In general, brochures and information that place a greater emphasis on reducing fear and anxiety and promoting active self-management have a greater opportunity for improving outcomes than traditional brochures that emphasize anatomy, ergonomics, and back-specific exercises.

Specific content recommendations include:

- Reinforcing the likely absence of serious disease when red flags are not present
- Hurt does not equal harm.
- Emphasize a good prognosis for low back pain. The majority of patients experience significant improvement in two to four weeks.
- Bed rest is not recommended and should be limited to no more than two days.
- Light activity will not further injure the spine and light activity typically helps speed recovery.
- A progressive resumption of work and activity levels leads to better short-term and long-term outcomes.
- Information and advice may be helpful regarding specific painful or limited activities such as sitting, lifting, getting up from bed, etc.

- No specific exercise type can be recommended as more effective. Examples of specific advice may include:
 - To take exercise as soon as back pain allows
 - Minimize bed rest, keep mobile, and increase walking time each day
 - Some of the easier sports to get back to after one has had back pain include walking or swimming.

Return to Work:

- Tell patients experiencing an episode of back pain that their pain is likely to improve and that the large majority of patients return to work quickly. They should understand that complete pain relief usually occurs after, rather than before, resumption of normal activities and their return to work can be before they have complete pain relief.
 Working despite some residual discomfort poses no threat and will not harm them.
- All persons recovering from back pain should understand that episodes
 of back pain may recur but can be handled similarly as the one from
 which they are recovering.
- Patients can reduce the likelihood of back pain recurrence by making exercise and lifestyle changes, as noted elsewhere.
- Consider using the following questions to guide your discussion about non-physical factors that can significantly impact risk for ongoing disability and return to work:
 - Do you enjoy the tasks involved in your job?
 - Do you get along with your closest or immediate supervisor?

Follow-Up Visit:

Because most patients with acute pain improve by 2 weeks, a conservative treatment approach is recommended. Low back pain patients who are not improving or who experience significant limitation of daily activity at home or work should contact their provider within 1 to 3 weeks of the initial evaluation. Patients who are improving should continue home self-care.

Red flag and psychosocial indicators should be reviewed and evaluated at each contact/visit. It is the consensus of the work group that an assessment that includes a subjective pain rating, functional assessment, and a clinician's objective assessment should be done at each visit.

It is the consensus of the work group that for patients who are improving, consider a follow-up with their provider. The benefit is to reinforce education and lifestyle changes that have enabled the patient to improve. This provides for outcome measures to be assesses as identified in the aims and measures section of the guideline.

Evidence supporting this recommendation is of classes: A, C, M, R

14. Consider Referral to a Spine Care Specialist

Key Points:

 A spine care specialist consistently demonstrates competency in providing therapies based on continuing education and effective techniques supported by literature.

Choice of the trained professional will be determined by availability and preference of individual medical providers and organization systems. The patient and/or physician should request a trained spine therapy professional who consistently demonstrates competency in providing therapies for patients with low back pain based on effective techniques supported by literature as outlined in this guideline.

These therapies include education, exercise programs, and appropriate use of manual/manipulative therapies. Individuals who may have training in these therapies include physical therapists, chiropractic providers, osteopathic or allopathic physicians.

The following should be considered when selecting a spine therapy professional who will effectively evaluate and treat the lumbar spine, pelvic girdle (including sacroiliac [SI] joint), and muscle imbalances (piriformis):

Physician or Therapist

- Participants in additional training and in ongoing continuing education courses in manual treatment of the spine
- Years of experience treating spine patients
- · Volume of patients treated for spine dysfunction in the past year
- Number of referrals an individual provider receives on a regular basis

Therapist

- Provides treatment interventions which include manipulation, exercise, and education
- Average number of visits per episode of care for low back pain
- Percentage of patients who return to previous level of activity

Indications for referral include:

- Failure to make improvement with home self-care after 2 weeks
- Severe incapacitating and disabling back or leg pain
- Significant limitation of functional or job activities

The professional's treatment plan should include both education and exercise. The treatment plan may include modalities, if necessary, to enable an individual to carry out an exercise program and self-care. It may also include limited passive treatments such as manual therapy (e.g., includes manipulation and mobilization) among others. Spinal manipulation should not be done if pre-manipulative testing peripheralizes symptoms.

Passive treatments are to be minimized and used only to progress an individual toward independence in exercise and self-care. Active treatment such as exercise must be introduced within a week of initiating passive treatments.

Within 3 to 4 visits, the patient must display documented improvement in order to continue therapy. If no improvement is noted, a comprehensive re-evaluation should be performed by the spine care professional for other causes of low back pain including regional SI joint dysfunction.

Continued improvement must be documented for continued therapy. Typically no more than 4 to 6 visits are needed.

After 9 visits the primary care provider should be consulted to continue therapy.

Evidence supporting this recommendation is of classes: A, M, R

17. Chronic Low Back Pain

A comprehensive re-evaluation including a general assessment (see Annotation #4, "Primary Care Evaluation and X-Ray Indications") should be done for patients not improving after 6 weeks. Most patients with acute back pain will improve within 6 weeks. Back pain and sciatica which persist longer than six weeks are defined as chronic.

An assessment that includes a subjective pain rating, functional assessment, and a clinician's objective assessment should be done.

See Annotation Appendix B, "Psychosocial Screening and Assessment Tools" in the original guideline document. See the NGC summary of ICSI guideline <u>Major Depression in Adults in Primary Care</u> for the diagnosis and treatment of depression.

For patients not improving after 6 weeks see "Lumbar Spine X-Rays (AP and LAT views) if Indicated" in this annotation and Annotation #22, "Chronic Sciatica" for imaging considerations.

Of the 10% of patients with chronic symptoms, 90% fall into the chronic LBP category and only 10% fall into the chronic sciatica category.

Physical factors which may lead to delayed recovery or prolonged disability include malignancy, infection, metabolic, or a bio-mechanical condition (e.g., sacroiliac joint dysfunction [SJD]). Consider blood testing (including CBC and erythrocyte sedimentation rate [ESR]) if there is suspicion of cancer or infection.

Clinical indicators for SJD include delayed recovery with unilateral pain below L5, pain near the posterior inferior iliac spine (PSIS), and, at times, radicular or referred pain to the groin, thigh, or below the knee. Diagnostic maneuvers for this condition include a positive Patrick's test, gapping test, compression

test and Gaenslen's test. Appropriate treatment by a trained spine professional will include manual therapy, instruction of self-corrective maneuvers, and strengthening exercises.

Referred pain from the sacroiliac joint can often refer into the lower extremity, even below the knee or into the foot. The most reliable locations include pain below L5, pain in the region of the posterior-superior iliac spine, and pain into the groin.

There is at least some theoretical support for active rehabilitation of the abdominal musculature in treating sacroiliac joint dysfunction by stabilizing the joint.

Lumbar Spine X-rays (AP and LAT views) if Indicated

Patients with chronic LBP or acute LBP who are not improving should receive consideration for further diagnostic testing. (See Annotation #4, "Primary Care Evaluation and Imaging Indications" above.) Oblique view x-rays are not recommended; they add only minimal information in a small percentage of cases, and more than double the exposure to radiation.

Several x-ray findings are of questionable clinical significance and may be unrelated to back pain. These findings include:

- Single disk space narrowing
- Spondylolysis
- Lumbarization
- Sacralization
- Schmorl nodes
- Spina bifida occulta
- Disk calcification
- Mild to moderate scoliosis

Evidence supporting this recommendation is of classes: C, M

18. Active Rehabilitation

There is strong evidence that exercise therapy is effective for chronic LBP. However, there is inconclusive evidence in favor of one exercise over the other--flexion, extension, fitness. [Conclusion Grade I: See Conclusion Grading Worksheet -- Appendix B -- Annotation #18 (Active Rehabilitation) in the original guideline document]. High-grade mobilization/manipulation has been shown to be effective early in treatment when followed by appropriate active rehabilitation.

The treatment of chronic low back pain should include:

- Education (back book and advice by provider)
- Active self management
- Gradual resumption of normal light activities as tolerated
- Prevention good body mechanics

- Exercise many studies show the benefit of an exercise program with chronic low back pain
 - Inconclusive evidence in favor of one exercise over the other (flexion, extension, or fitness)
 - Consider a graded active exercise program.
 - Consider specific exercises to strengthen the core trunk stabilizing muscles.
 - Consider intensive exercise program.
- Assess and manage psychosocial factors
- Multidisciplinary approach

Evidence supporting this recommendation is of classes: A, B, C, D, M, R

20. Refer/Consult Non-Surgical Back Specialist

Each medical group may have other indications for specialty referral.

Indications for specialty referral may include:

Physiatrist/physical medicine and rehabilitation

- Chronic back pain for longer than 6 weeks
- Chronic sciatica for longer than 6 weeks
- Chronic pain syndrome
- Recurrent back pain

Medical orthopedics

- Chronic back pain for longer than 6 weeks
- Chronic sciatica for longer than 6 weeks

Neurology (limited special indications)

- Chronic sciatica for longer than 6 weeks
- Atypical chronic leg pain (negative straight leg raise)
- New or progressive neuromotor deficit

Occupational medicine (limited special indications)

- Difficult Workers' Compensation
- Disability/impairment ratings
- Return to work issues

Rheumatology (limited special indications)

- Rule out inflammatory arthropathy
- Rule out fibrositis/fibromyalgia
- Rule out metabolic bone disease (e.g., osteoporosis)

Evidence supporting this recommendation is of class: R 23 of 38

22. Chronic Sciatica

Key Points:

 Magnetic resonance imaging (MRI) and computed tomography (CT) are not useful during acute sciatica unless red flag indications are present.

See Annotation #17, "Chronic Low Back Pain" for a comprehensive physical and psychosocial evaluation including a subjective pain assessment, functional assessment, and a clinician's objective assessment.

MRI or Lumbar Spine CT I maging Indications When Patient is a Potential Surgical Candidate

MRI and CT generally are not useful during acute low back pain or acute sciatica unless surgery, cancer, or infection are considerations (red flag indications). MRI or CT can be ordered by a primary care provider in consultation with an appropriate consultant when the patient meets surgical referral criteria. (See Annotation #24, "Consider Epidural Steroid Injections Prior to Surgical Intervention.") Each medical group may have specific arrangements for ordering CT, MRI, or other special diagnostic tests prior to referral to a surgical back specialist.

In isolated cases of low back pain without radicular symptoms, MRI is the preferred diagnostic test. However, in an otherwise healthy adult without a previous history of back surgery and symptoms of low back pain with radicular symptoms, a CT scan may be as sensitive as an MRI.

The Adult Low Back Pain guideline work group has listed advantages for both CT and MRI imaging and a list of conditions for each. This list is not meant to be comprehensive but to aid the clinician in making a decision.

MRI Indications:

- Major or progressive neurologic deficit (e.g., foot drop or functionally limiting weakness such as hip flexion or knee extension)
- Cauda Equina syndrome (loss of bowel or bladder control or saddle anesthesia).
- Progressively severe pain and debility despite conservative therapy
- Severe or incapacitating back or leg pain (e.g., requiring hospitalization, precluding walking, or significantly limiting the activities of daily living).
- Clinical or radiological suspicion of neoplasm (e.g., lytic or sclerotic lesion on plain radiographs, history of cancer, unexplained weight loss, or systemic symptoms).
- Clinical or radiological suspicion of infection (e.g., endplate destruction of plain radiographs, history of drug or alcohol abuse, or systemic symptoms).
- Trauma (fracture with neurologic deficit, compression fracture evaluation in elderly patients with question of underlying malignancy,

- characterization in anticipation of vertebroplasty/kyphoplasty, stress fracture or subacute spondylosis in a patient less than 18 years of age).
- Severe low back pain or radicular pain, unresponsive to conservative therapy, with indications for surgical intervention.

For patients with mild to moderate claustrophobia, 5 to 10 mg of benzodiazepine 1-hour prior to scan is effective. The patient will need to be accompanied by a driver.

MRI Advantages

- Better visualization of soft tissue pathology. Better soft tissue contrast
- Better visualization of neurological structures
- Improved sensitivity for cord pathology and for intrathecal masses
- Improved sensitivity for infection and neoplasm
- No radiation exposure
- Safer for women who are pregnant, especially in the 1st trimester due to no radiation exposure

CT Indications:

- Major or progressive neurologic deficit (e.g., foot drop or functionally limiting weakness such as hip flexion or knee extension)
- Cauda Equina syndrome (loss of bowel or bladder control or saddle anesthesia).
- Progressively severe pain and debility despite conservative therapy
- Clinical or radiological suspicion of neoplasm (e.g., lytic or sclerotic lesion on plain radiographs, history of cancer, unexplained weight loss, or systemic symptoms)
- Bone tumors (to detect or characterize)
- Severe or incapacitating back or leg pain (e.g., requiring hospitalization, precluding walking, or significantly limiting the activities of daily living).

CT Advantages

- Better visualization of calcified structures
- Direct visualization of fractures
- Direct visualization of fracture healing and fusion mass
- More accurate in the assessment of certain borderline or active benign tumors
- More available and less costly
- Better accommodation for patients over 300 lbs and patients with claustrophobia
- Safer for patients with implanted electrical devices or metallic foreign bodies
- Less patient motion. Particularly useful for patients who cannot lie still or for patients who cannot cooperate for an MRI

Other special diagnostic tests such as myelogram, electromyography (EMG), radio nuclide studies (RNS), and bone scan should be ordered as each medical 25 of 38

group dictates and consider the preference of the specialist when referral is planned.

See Annotation Appendix C, "CT and MRI Order Sets" in the original guideline document.

Evidence supporting this recommendation is of classes: C, R

24. Consider Epidural Steroid Injections Prior to Surgical Intervention

Key Points:

• Epidural steroid injects should be performed under fluoroscopy with contrast for best results.

The goal of epidural steroid injections in patients with back or leg pain and stenosis or a herniated disc on MRI or CT is pain control and functional improvement. Several studies have shown that a single epidural injection affords short-term relief of pain.

Multiple injections are administered over a period of time in order to realize the natural history of the patient's disease. The frequency and number of injections are determined by the response to the first injection, by the patient's preferences, and by the referring physician. If the patient's pain can be controlled, 70 to 90% will achieve good or excellent results at one year without surgery. With multiple injections, several authors have shown excellent results at one year: Botwin 75% at 1 year, Lutz 75% at 80 weeks, Vad 84% at 1 year.

As previously mentioned, injections should be performed under fluoroscopy and with contrast in order to deliver cortisone as close to the disc herniation, area of stenosis, or nerve root impingement as determined by MRI or CT, and with as little morbidity as possible. Failure of treatment may result from a failure to deliver medications to the treatment field. Failure to deliver medication to the treatment field may be related either to the approach or to patient variables:

- 1. Epidural fibrosis can result in the preferential flow of medication away from a recurrent disc herniation.
- 2. Caudal injections may fail to deliver medication above L5-S1, particularly in patients with central canal stenosis.
- 3. Translaminar injections may localize preferentially to the dorsal epidural space.
- 4. Transforaminal injections may localize preferentially to the peripheral perineural space particularly in the setting of severe foraminal stenosis.

No study has shown a clear advantage of one approach (interlaminar, caudal, or transforaminal), type of cortisone or volume of injectate. The approach needs to be individualized to each patient.

Procedural morbidity also varies with each approach. With interlaminar injections there is a risk of intrathecal injection and subsequent arachnoiditis, as well as post-procedural headaches. With transforaminal injections, patients frequently report significant, although in most cases transient, leg pain and there is a risk of spinal cord infarction.

Approach and drug combination should be the choice of the proceduralist and should be dictated by the location and type of pathology and anatomical constraints of the given patient. For example, the initial injection for a patient with a paracentral disc herniation or subarticular recess stenosis might be interlaminar since this procedure is relatively painless and has a very low morbidity. If the injection results in several weeks or months relief of pain, the procedure would be repeated if the patient returns for a second injection. If the response to the initial injection is limited, however, a transforaminal injection might be performed at the time of the second injection or an interlaminar injection could be performed at a different level. Specification of the approach by the provider can on occasion dictate a suboptimal approach (e.g., a transforaminal approach in a patient with severe foraminal stenosis) and also limits the ability of the proceduralist to adjust the procedure given the experience with the first injection.

Oral steroids should be discontinued for 1 week prior to epidural procedure.

Patient Selection

- Patients should have predominantly complaints of leg pain in a
 dermatomal distribution with corroborative examination findings for
 radiculopathy (reflex changes, possible motor weakness, and root
 tension signs.) In addition, the pain should be of the severity that
 significantly limits function and quality of life and has not responded to
 oral analgesic medications and other conservative care measures.
- Corroborative neural axis imaging is required, either MRI or CT, with evidence of disk disease or bony stenosis which fits with the clinical syndrome.
- Patients should have no contraindications to injection therapy, including:
 - No signs or symptoms of active infection either systemically or locally
 - No history of bleeding disorders or current use of anticoagulants such as warfarin or clopidogrel; allow the patient to "drift" to the lowest effective International Normalized Ratio (INR) prior to procedure
 - No allergies to local anesthetic agents, contrast agents, or corticosteroids
 - No prior complications to corticosteroid injections

Pregnancy is a contraindication for the use of fluoroscopy. Caution should be used in diabetic patients because of altered glycemic control, which is typically transient. Also, patients with congestive heart failure need to be aware of steroid-induced fluid retention. Though non-steroidal anti-inflammatory drug (NSAID) use is not a

contraindication to injections, some practitioners discontinue NSAIDs several days prior to injection.

- Informed consent of the patient with knowledge of potential side effects and complications of epidural injection therapy
- The prime goal of epidural steroid injection therapy is pain relief.

Technical Issues

- Epidural steroid injections should be performed by an experienced provider using image guidance and contrast control. Epidural injections performed without fluoroscopic guidance and contrast control (i.e., "blind epidural injections") are not recommended and are known to miss the perceived target tissue 18 percent to 52 percent of the time depending on the experience of the provider. Image guidance and contrast control are used to ensure that the injection is not performed intravascularly, intrathecally, or in tissues other than the epidural space.
- Route of administration and efficacy:
 - Interlaminar injections These are performed approaching the epidural space just lateral to the spinous processes of adjacent vertebrae. The efficacy of laminar injections has been reviewed with mixed results. However, studies generally suffer from lack of a control group, lack of image guidance, or failure to adequately identify the target tissue.
 - Transforaminal injections -- These are performed placing the
 medication through the intravertebral foramen with the
 theoretical advantage of ensuring that the medication reaches
 the target tissue in the anterior epidural space. Two controlled
 trials have demonstrated efficacy and supported the positive
 results of other less-controlled studies. However, there is an
 obvious need for outcome data with an emphasis on return of
 function and not simply pain control and avoidance of surgery.

Evidence supporting this recommendation is of classes: A, R

25. Refer/Consult Surgical Back Specialist

Key Points:

- The appearance of a disc herniation does not rule out a course of conservative therapy. Unless red flag indications are present, all patients should undergo a trial of conservative therapy.
- The decision to operate is a clinical decision based on the presence of severe, uncontrolled pain, profound or progressive neurological symptoms, or a failure to respond to conservative therapy.

Special diagnostic tests can be used to help clinicians decide the appropriate referral to a specialist. To decide which test, consult with subspecialty physicians.

- Bone scan (limited with single photon emission computer tomography [SPECT])
- EMG (electromyography)
- CT enhanced myelogram
- Myelogram
- RNS (radionuclide studies)

Neurosurgery or orthopedic surgery

- Patient is surgical candidate.
- Cauda Equina Syndrome
- Progressive or severe neuromotor deficit (e.g., foot drop or functional muscle weakness such as hip flexion weakness or quadriceps weakness)
- Persistent neuromotor deficit after 4 to 6 weeks of conservative treatment (does not include minor sensory changes or reflex changes)
- Chronic sciatica with positive SLR for longer than 4 to 6 weeks
- Uncontrolled pain

Patients with large, extruded, sequestered, or high signal intensity disc herniations do not have a worse prognosis than do patients with smaller contained disc herniations or protrusions. The presence of a disc extrusion or sequestration is not an indication for immediate surgery.

- The appearance of a disc herniation on MRI/CT (including extruded/sequestered disc) does not determine whether an individual patient will respond to conservative therapy. Assuming that the patient's pain can be controlled and that no red flags or contraindications exist, all patients should undergo a trial of conservative therapy.
- The decision to operate is a clinical one, not a radiologic one, and is generally based on the presence of severe, uncontrolled pain, profound or progressive neurological symptoms, or a failure to respond to conservative therapy.
- Even though it was not discussed above, it is important to emphasize the concept that a disc herniation on MRI/CT is of relevance only with respect to specific clinical symptoms. Disc herniations can be seen in asymptomatic patients, and one can surmise from the literature quoted that if a patient's symptoms resolve and the disc herniation does not resorb, it will be present on the next examination.

Evidence supporting this recommendation is of classes: A, C, D, R

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with

negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

• Randomized, controlled trial

Class B:

Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report
- B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

Meta-analysis

- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Adult Low Back Pain.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., activity recommendations for patients with acute low back pain; exercise therapy for patients with chronic back pain) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate medical evaluation, treatment, and management of low back pain in adults including:

- Appropriate use of conservative treatment as a first-line approach
- Reduced use of unnecessary imaging studies
- Appropriate assessment of patients with chronic low back pain

POTENTIAL HARMS

Strengthening Exercises

During the first 2 weeks, strengthening exercises may aggravate symptoms since they mechanically stress the back more than endurance exercise.

Epidural Steroid Injection

- Caution should be used in diabetic patients because of altered glycemic control which is typically transient. Also, patients with congestive heart failure need to be aware of steroid-induced fluid retention.
- With interlaminar injections there is a risk of intrathecal injection and subsequent arachnoiditis, as well as post-procedural headaches. With transforaminal injections, patients frequently report significant, although in most cases transient, leg pain and there is a risk of spinal cord infarction.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Fluoroscopy: Contraindications include pregnancy.
- Steroid injections: Contraindications include patients with signs and symptoms of active infection either systemically or locally, history of bleeding disorders or current use of anticoagulants such as warfarin or clopidogrel, allergies to local anesthetic agents, contrast agents, or corticosteroids, prior complications to corticosteroid injections.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This clinical guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- The Adult Low Back Pain guideline work group has listed advantages for both computed tomography (CT) and magnetic resonance imaging (MRI) and a list of conditions for each. This list is not meant to be comprehensive but to aid the clinician in making a decision.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms Clinical Algorithm Patient Resources Pocket Guide/Reference Cards Quality Measures Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NOMC MEASURES

• Adult low back pain: percentage of patients with acute low back pain receiving anterior-posterior (AP) or lateral (LAT) x-rays.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Adult low back pain.
Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Sep. 64 p. [115 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1994 Jun (revised 2005 Sep)

GUI DELI NE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUI DELI NE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

GUIDELINE COMMITTEE

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: David C. Thorson, MD (Work Group Leader) (Family HealthServices Minnesota) (Sports Medicine); Julie Vaneck, MD (Fairview Health Services) (Family Medicine); Robb Campbell, MD, MPH (3M) (Occupational Medicine); Ola Kuku, MD, MPH (Allina Medical Clinic) (Occupational Medicine); Peter Marshall, MD (HealthPartners Medical Group) (Occupational Medicine); Randy Shelerud, MD (Mayo Clinic) (Physical Medicine and Rehabilitation); Richard Timming, MD (HealthPartners Medical Group) (Physical Medicine and Rehabilitation); Thomas Gilbert, MD (Center for Diagnostic Imaging) (Radiology); Kelly Albers, PT (Park Nicollet Health Services) (Physical Therapy); Steve Peterson, PT (Orthopaedic Sports, Inc.) (Physical Therapy); Penny Fredrickson (Institute for Clinical Systems Improvement) (Measurement Advisor); Brent Metfessel, MD, MPH (Institute for Clinical Systems Improvement) (Evidence Analyst); Sherri Huber, MT (ASCP) (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Adult low back pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Sep. 63 p.

GUIDFLINE AVAILABILITY

Electronic copies: Available from the <u>Institute for Clinical Systems Improvement</u> (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Adult low back pain. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Sep. 2 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- Functional ability questionnaire and Oswerty low back pain scale. Annotation Appendix A. in the original guideline document. Electronic copies: Available from the <u>Institute for Clinical Systems Improvement (ICSI) Web site</u>
- Psychosocial screening and assessment tools. Annotation Appendix B in the original guideline document. Electronic copies: Available from the <u>Institute for</u> <u>Clinical Systems Improvement (ICSI) Web site</u>
- CT and MRI order sets. Annotation Appendix C in the original guideline document. Electronic copies: Available from the <u>Institute for Clinical Systems</u> Improvement (ICSI) Web site
- ICSI pocket guidelines. May 2005 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2005. 362 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

The following is available:

• Adult low back pain. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Oct. 31 p.

Electronic copies: Available from the <u>Institute for Clinical Systems Improvement</u> (ICSI) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 30, 1999. The information was verified by the guideline developer on August 4, 1999. This summary was updated by ECRI on October 13, 2000 and January 8, 2002. This summary was updated most recently on March 14, 2003. The updated information was verified by the guideline developer on May 15, 2003. This summary was updated again on April 26, 2004 and October 13, 2004. This summary was updated by ECRI on January 12, 2005 following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of some non-steroidal anti-inflammatory

drug products. This summary was updated on April 15, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI most recently on October 20, 2005.

COPYRIGHT STATEMENT

This NGC summary (abstracted Institute for Clinical Systems Improvement [ICSI] Guideline) is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

The abstracted ICSI Guidelines contained in this Web site may be downloaded by any individual or organization. If the abstracted ICSI Guidelines are downloaded by an individual, the individual may not distribute copies to third parties.

If the abstracted ICSI Guidelines are downloaded by an organization, copies may be distributed to the organization's employees but may not be distributed outside of the organization without the prior written consent of the Institute for Clinical Systems Improvement, Inc.

All other copyright rights in the abstracted ICSI Guidelines are reserved by the Institute for Clinical Systems Improvement, Inc. The Institute for Clinical Systems Improvement, Inc. assumes no liability for any adaptations or revisions or modifications made to the abstracts of the ICSI Guidelines.

DISCLAIMER

NGC DISCLAIMER

The National Guideline ClearinghouseTM (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 3/13/2006